

SHIMKUS MEDICAL DEVICE PROVISIONS IN 21ST CENTURY CURES ACT

(H.R. 2422) Section 2221—Third-Party Qualification System Assessment

Reviewing minor modifications to devices or manufacturing processes can cost companies and FDA a lot of time and resources. This section would give companies, with qualification systems certified as capable of evaluating changes, the ability to make these types of modifications without prior FDA approval. The goal is to ensure safety and innovation while reducing FDA's workload in this area to free up resources for more complex reviews.

(H.R. 2423) Section 2222—Valid Scientific Evidence

This section is intended to give FDA more information and data to review company submissions. It would allow FDA to consider collected registry data and peer reviewed journal studies from around the world.

(H.R. 2424) Section 2203—Training and Oversight in Least-Burdensome Means Concept

For nearly two decades, a policy has been in place at FDA requiring they only collect evidence necessary to evaluate device submissions. This policy has been inconsistently applied. To provide more clarity and consistency, this section would require training on the meanings and implementation of the 'least burdensome' concept for all FDA staff who review premarket medical device submissions. FDA would also be required to maintain a guidance document on the concepts and principles of the 'least burdensome' provisions as a resource for the agency moving forward.

(H.R. 2425) Section 2204—Recognition of Standards

As global products, medical devices are subject to standard settings organizations around the world. Manufacturers, regulators and the FDA themselves often participate in the standard setting process, but when it comes to utilizing these consensus standards as a resource, FDA has been inconsistent. This section would allow any person to submit a request to FDA to recognize these standards as appropriate, and require FDA to respond in writing with their determination and justification for whether or not to recognize all, part or none of the standard. FDA would also be required to provide guidance and training to the appropriate staff on the concept and use of recognized standards for premarket device submission requirements.

(H.R. 2426) Section 2205—Notification of Marketing of Certain Class I Devices

This section will allow FDA to finally remove Class I devices from the reserve list they have determined no longer require additional information to prove reasonable assurance of safety and effectiveness. The section would also give FDA the tools necessary to create a similar list of Class II devices they believe meet these same criteria.

(H.R. 2427) Section 2206—Advisory Committee Process

This section would increase the transparency of the panel member selection process and provide an opportunity for the sponsor to participate in the discussions. It will also establish criteria to include advisory committee members with a specialty or other expertise clinically relevant to the device under review.

(H.R. 2428) Section 2207—Humanitarian Device Exemption Application

Recognizing the unique challenges facing approval for devices used to treat or diagnose medical conditions affecting only a very small population, Congress provided a humanitarian exemption for devices used in situations where fewer than 4,000 individuals are affected by a disease in the United States in a given year. This section would raise the arbitrary 4,000 person threshold – doubling it to 8,000 – to expand the universe of patients that could benefit from a HDE.